uniphy
Elektromedizin

MAR 1 5 2006

Uniphy Elektromedizin GmbH & Co. KG
Neuendorfstraße 19 b
D-16761 Hennigsdorf
Germany

Abbreviated 510(k) submission for cryflow 700 and cryflow 1000.

510(k) Summary

K052310

Date prepared: August 19, 2005

Submitter:
Uniphy Elektromedizin GmbH & Co. KG
19B Neuendorferstraße
16761 Hennigsdorf
Germany
Contact Name: ... Reiner Tostmann, Doc-Eng
Phone Number: .. 11-49-3302-50440
FAX Number: 11-49-3302-504499
E-mail: ..... Reiner.Tostmann@uniphy-elmed.com

Device trade name: Cryoflow 700, Cryflow 1000

Common name: Skin Refrigerant

Classification name: Class 2 (21CFR 878.4810) 78 GEX
Laser surgery instrument for use in general and plastic surgery and dermatology.

Description of device: The Cryoflow 700 and Cryoflow 1000 consists of a refrigeration unit that creates cold air. The cold air is blown onto the skin using an air hose.

Performance Standards: None established (as a medical device) under section 514.

Intended use of the device: The Cryoflow 700 and Cryoflow 1000 are intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Substantial equivalence claim to the following legally marketed device:
Cryo 5 (Zimmer). K040727

Summary of substantial equivalence:

The Uniphy Cryoflow 700 and Cryflow 1000 are substantially equivalent to the compared device on the basis of similarities in operating principles, intended use and functional performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Gymnauniphy N.V.
c/o Nico Beun
Uniphy Elektromedizin GmbH & Co. KG
Pasweg 6A
Belzen 3740
Belgium

Re: K052310
Trade/Device Name: Cryoflow 700, Cryflow 1000
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 22, 2005
Received: August 24, 2005

Dear Nico Beun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DCN: K052310

uniphy
Elektromedizin

Uniphy Elektromedizin GmbH & Co. KG
Neuendorfstraße 19 b
D-16761 Hennigsdorf
Germany

Indications for Use

510(k) Number (if known): K052310

Device Name: Cryoflow 700, Cryoflow 1000

Indications for Use:

- The Cryoflow 700 and Cryoflow 1000 are intended to minimize pain and thermal injury during laser and dermatological treatments and for temporary topical anesthetic relief for injections.

Prescription Use __Yes__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052310

(Posted November 13, 2003)